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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,340	06/27/2001	Robert A. Rousseau	ETH-1507	3554
27614	7590	09/10/2004		
RALPH W. SELITTO, JR. C/O MCCARTER & ENGLISH, LLP GATEWAY CENTER FOUR 100 MULBERRY STREET NEWARK, NJ 07102			EXAMINER LANDREM, KAMRIN R	
			ART UNIT 3738	PAPER NUMBER

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/892,340

Applicant(s)

ROUSSEAU, ROBERT A.

Examiner

Kamrin R. Landrem

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 21, 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6,14, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Chaffrignon et al (USPN 5,919,232).

With reference to Figure 1, Chaffrignon discloses a prosthetic mesh system 1 adapted for implantation into an area containing a hernia defect (2:64) comprising a flexible biocompatible mesh 10 that has a generally flat shape (Figure 1) and a second generally collapsed shape (Figures 2 and 5). The mesh layer 10 has a plurality of ridges 5 formed integrally there within to facilitate movement of the mesh layer 10 from a flat to a generally collapsed configuration. The mesh layer is expandable from its collapsed shape to its flat shape after being implanted in the body (4:12-20).

With regards to Claim 2, this is considered a product by process claim. MPEP 2111 states, “Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” Chaffrignon does not specifically recite that a thermo-forming process forms the device however the product formed is the same and is

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therefore rejected in view of Chaffrignon. In addition the applicant's specification, page 5, lines 18-21 disclose that other processes can be used for shaping the patch so as to provide ridges therein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chaffrignon in view of Kugel (USPN 5,634,931).

Chaffrignon, as discussed above, discloses the prosthetic mesh system as claimed. Chaffrignon however does not disclose a mesh comprising two layers. With reference to Figure 5 Kugel teaches a hernia mesh patch (7:36-60) composed of a top 42 and a bottom layer 44 thus enabling the surgeon to place his or her finger between the layers and easily insert the patch (4:15-26). A ring 72 connects the layers 42,44. Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the mesh system as disclosed by Chaffrignon to have two layers thus allowing the surgeon to easily insert the mesh with less tension, less post-operative discomfort, shorter operating time, and a lower potential cost to the patient (5:33-43).

Claims 9-13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Chaffrignon.

Chaffrignon discloses the prosthetic mesh as discussed above. Chaffrignon does not disclose expressly a mesh comprising ridges in multiple formations. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have formed the ridges into concentric circles or radial extensions from the center because Applicant has not disclosed that these ridge formations provide an advantage, are used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with ridges paralleling one another as taught by Chaffrignon because these ridges facilitate the movement of the mesh layer between a collapsed and a flat shape by pulling or releasing said ridges.

Therefore, it would have been an obvious matter of design choice to modify Chaffrignon to obtain the invention as specified in claims 9-13.

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chaffrignon et al in view of White (USPN 5,728,510).

As discussed above, Chaffrignon discloses a prosthetic mesh system adapted for implantation in a body, comprising a biocompatible mesh layer wherein the mesh layer is flexible such that it has a generally flat shape and a generally collapsed shape for insertion. Chaffrignon discloses the claimed prosthetic mesh however fails to disclose that the mesh comprises at least one ridge formed monolithically with said mesh layer to form a single piece. With reference to Figures 1 and 2, White teaches a prosthetic mesh 1 having a plurality of ridges 40 formed as a single monolithic sheet that has variable flexibility (4:56-5:2) depending on the specific use of the mesh that is adapted for implantation into a body and provides a material

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which simulates human tissue for use in repair and replacement of tissue at a lower cost (1:59-2:22). Chaffrignon includes embodiments of multiple layers (Figure 8) or single layers (single piece Figures 5-7). Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the mesh of Chaffrignon by including the ridge as a single piece to form the monolithic mesh as taught by White to form a more cost effective, biocompatible material for repair and replacement of tissues.

Response to Arguments

Applicant's arguments filed 6/1/04 have been fully considered but they are not persuasive. The applicant's arguments of Claim 1, with regards to the "mesh layer with at least one ridge formed integrally therewith" are unpersuasive. The term "integrally" is interpreted to mean "something made up of parts that together form a whole". Therefore the filament (ridge) that is interlaced at catching points within the mesh. Therefore the filament part and the woven mesh structure, together form an integral prosthetic mesh system. The filaments are shaped and configured to facilitate the mesh to move from a flat configuration, to a collapsed configuration for insertion, and back to a flat deployed configuration (4:12-20). Chaffrignon et al further discloses that the mesh comprises a warp and weft configuration of polyester that is coated with collagen. Chaffrignon does not disclose that the mesh material comprises various materials and therefore the mesh material is internally consisted in material properties (i.e. rigidity) throughout.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamrin R. Landrem whose telephone number is 703-305-8061. The examiner can normally be reached on 8:00-5:00, Monday-Friday.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kamrin Landrem
Examiner
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